

REMARKS

Reconsideration of the outstanding rejections is respectfully requested for the reasons that follow.

Claim Objections

Claim 7 was objected to for a typographical error. Applicants submit that claim 7 as amended overcome the objection.

Priority

The related application data as amended correctly reflects the priority information in the supplemental application data sheet submitted on December 30, 2004. The typographical error is corrected, and the status of the applications is updated.

Double Patenting

Claims 1-8 and 11 were rejected under the doctrine of double patenting over claims 1-6 of U.S. Patent No. 6,551,801. Applicants note that claim 11 is cancelled. Applicants submit that claims 1-8 as amended recite a process that does not produce a dimeric bone morphogenetic factor. Therefore, it is submitted that the double patenting rejection is overcome.

Claim Rejections – 35 U.S.C. § 103

Claims 1-3, 6 and 8 were rejected under 35 U.S.C. §103 as being unpatentable over Wolfman (U.S. 5,399,677) in view of Cerletti (EP 0433225).

Initially, it is noted that claim 1 as amended is directed to a process for the production of a purified refolded biologically active monomeric bone morphogenetic factor of which amino acid sequence is modified to not form an intermolecular disulfide bond with another bone morphogenetic factor monomer. Applicants submit that none of Cerletti and Wolfman, alone or combined, teaches or suggests such a process. Applicants submit that a person having ordinary skill in the art ("Phosita") would not only have had no motivation to modify the combination of Cerletti and Wolfman to reach the claimed process, but also have been taught away from the claimed process by Cerletti.

The goals or purposes of Cerletti and Wolfman are the same, namely producing a biologically active dimeric bone morphogenetic factor. See abstracts. As the Patent Office notes in the outstanding Office Action, the processes of Cerletti and Wolfman may incidentally produce a monomeric bone morphogenetic factor; however, it is submitted that the processes probably would not have produced a biologically active monomeric bone morphogenetic factor. Further, there is no doubt that the processes of Cerletti and Wolfman does not produce a purified refolded biologically active monomeric bone morphogenetic factor of which amino acid sequence is modified to not form an intermolecular disulfide bond with another bone morphogenetic factor monomer. Such a modified bone morphogenetic factor is not taught or suggested anywhere in Cerletti and Wolfman.

Rather, Cerletti teaches or suggests that monomeric bone morphogenetic factors, particularly ones not forming intermolecular disulfide bonds, are not biologically active. See page 2, line 55-page 3, line 5. The portion cited in the Office Action, page 8, lines 19-24, only teaches denatured sulfonated monomers to prevent premature intermolecular disulfide bond formation, and Cerletti makes it clearly the formation of an intermolecular disulfide bond is critical in obtaining a biologically active dimers. See page 5, lines 28-29.

Therefore, it is submitted that claim 1 and all claims depending from claim 1 are patentable over the combination of Cerletti and Wolfman. Further, it is submitted that new claim 18 is also patentable over the combination of Cerletti and Wolfman for the same reasons set forth in connection with claim 1, and also because the processes of Cerletti and Wolfman will inherently produce a solution containing at least a minor amount of dimeric bone morphogenetic factors formed by an intermolecular disulfide bond.

Claims 1 and 7 were rejected under 35 U.S.C. 103 as being unpatentable over the combination of Wolfman, Cerletti and Morishita (U.S. 5,840,518). It is submitted that Morishita does not cure the defects of the combination of Wolfman and Cerletti as set

forth above in connection with the rejections of claims 1-3, 6 and 8; therefore claims 1 and 7 are patentable over the combination of Wolfman, Cerletti and Morishita. Further, it is submitted that new claim 18 is also patentable for the same reasons set forth above.

In view of the foregoing, it is submitted that the present application is now in condition for allowance. Reconsideration and allowance of the pending claims are requested. The Director is authorized to charge any fees or overpayment to Deposit Account No. 02-2135.

Respectfully submitted,

By 

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